510(K) Summary

JUN 16 2011

Apex K1 ™ Hip Stem 16 April, 2011

Submitter OMNIlife science, Inc.
50 O'Connell Way
E. Taunton MA 02718

Contact Radhika Pondicherry
Regulatory Affairs
774-226-1852
(508) 822-6030 (fax)

Preparation Date 16 April ,2011

Device Name Apex Hip System
Trade Name Apex K1 ™ Hip Stem,

Sizes
Apex K1™ Hip Stem, Size 0
Apex K1™ Hip Stem, Size 0 Lat
Apex K1™ Hip Stem, Size 1
Apex K1™ Hip Stem, Size 1 Lat
Apex K1™ Hip Stem, Size 7 Lat +
Apex K1™ Hip Stem, Size 8 Lat +
Apex K1™ Hip Stem, Size 9 Lat +
Apex K1™ Hip Stem, Size 10 Lat +
Apex K1™ Hip Stem, Size 11 Lat +
Apex K1™ Hip Stem, Size 12 Lat +

Common name/ Classification
Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

Regulatory Class Class II per 21 CFR §888.3358, §888.3353, §888.3390
Product Code LPH, LZO,KWY
Legally Marketed Predicate Device(s) K060072- Apex K1™ Hip Stem

Device Description
The Apex K1™ Hip Stems are rectangular in cross-section and tapered in the proximal-to-distal direction. The K1 Hip Stem is offered in 12 sizes and two neck offsets for each size. Standard necks have a 135 degree angle and lateralized (Lat) necks have a 130 degree angle. Sizes 7 to 12 also offer a Lat + offset with a 127 degree angle.

Indications for Use
The Apex Hip System K1™ Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement when used with the Apex Interface™ Acetabular System. The Apex Interface™ Acetabular System articulates with the Apex Modular Femoral Head (Cobalt Chromium or Ceramic). The femoral hip stem is intended for uncemented fixation and single use implantation. These prosthesis may be used for hip arthroplasty to treat the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;

- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

The Apex Hip System K1 Femoral Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head.

The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other treatments or devices for these indications have failed.

Predicate Device Comparison

	Apex K1 Hip Stem, size 0, 0 Lat, 1, 1 Lat and 7 thru 12 Lat + (subject device)	**Apex K1 Hip Stem, Sz 2 to 12 (K060072)**
Intended Use		
Primary and revision total hip replacement	Yes	Yes
Design		
Stem Design	Identical to K060072	Rectangular in cross-section and tapered in the proximal-to-distal direction
Materials		
K1 Stem	Identical to K060072	Ti6Al4V per ASTMF136
Plasma spray Titanium coating	Identical to K060072	Ti Coating per ASTM F1580
PACKAGING AND STERILIZATION		
Sterilization	Identical to K060072	Ethylene oxide
Sal	Identical to K060072	10^{-6}
Packaging	Identical to K060072	Paper Board Box, Double Tyvek inner pouch

Non-Clinical Test Summary

The following tests were conducted:

- Fatigue Strength Testing per ISO 7206-6, ISO-7206-4, ISO 7206-8 and ASTM 2068-09
- ROM evaluation per ISO 21535

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Apex K1 Stems, sizes 0, 0 Lat, 1, 1 Lat, Lat + stems sizes 7,8,9,10,11 and 12 are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OMNIlife Science, Inc.
% Ms. Radhika Pondicherry
Regulatory Affairs Specialist
50 O'Connell Way
East Taunton, Massachusetts 02718

JUN 16 2011

Re: K110947
Trade/Device Name: Apex K1 Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWY
Dated: May 17, 2011
Received: May 18, 2011

Dear Ms. Pondicherry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin J. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K110947

Indications for Use

510(k) Number: K110947

Device Name: Apex K1™ Hip System

The Apex Hip System K1™ Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement when used with the Apex Interface™ Acetabular System. The Apex Interface™ Acetabular System articulates with the Apex Modular Femoral Head (Cobalt Chromium or Ceramic). The femoral hip stem is intended for uncemented fixation and single use implantation. These prosthesis may be used for hip arthroplasty to treat the following conditions, as appropriate:

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- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

The Apex Hip System K1 Femoral Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head.

The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other treatments or devices for these indications have failed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110947